

Remarks

Claims 25 and 30-39 are pending in the subject application and currently before the Examiner. Applicants gratefully acknowledge the Examiner's withdrawal of the previous rejections under 35 USC §112, first and second paragraphs, and 35 USC §102(b). Favorable consideration of the pending claims is respectfully requested.

Claims 25 and 30-39 are rejected under 35 USC §103(a) as obvious over Pene *et al.* (1988), Gruschwitz *et al.* (1993), or Kimata *et al.* (1995), and further in view of Johnson *et al.* (WO 97/39127). The Examiner cites the primary references as teaching the use of interferon alpha to downregulate IgE production. While acknowledging that the primary references do not teach downregulation of IgE production by interferon tau, the Examiner asserts that it would have been obvious to substitute interferon tau for interferon alpha in view of the Johnson *et al.* reference which, according to the Examiner, teaches that interferon alpha and interferon tau bind to the type I receptor and have similar biological activities. The Johnson *et al.* reference is also cited as teaching interferon chimeras. Applicants respectfully traverse this grounds of rejection.

Applicants respectfully assert that the claimed invention is not obvious over the cited references, regardless of whether the references are taken alone or in combination. Attached with this Response is a Declaration Under 37 CFR §1.132 by Dr. Howard M. Johnson. In his Declaration, Dr. Johnson explains why a person of ordinary skill in the art at the time of the invention would not have predicted that interferon tau, or a chimera of interferon tau, would function to downregulate IgE production. Dr. Johnson supports his statements and conclusions with evidence and scientific publications. Applicants acknowledge that certain of the publications cited by Dr. Johnson were published after the filing date of the subject application. However, these references are offered to show that there remains, even in the present day, uncertainty as to functional activities of interferon tau and interferon alphas. Dr. Johnson points out in his Declaration that even among the various interferon alpha species, there are functional differences and, therefore, an ordinarily skilled artisan could not reasonably predict the functional activity of one species of interferon based on the observed function of another species of interferon. In addition, Dr. Johnson also points out in his Declaration that even today it is not known exactly what genes are activated by interferon tau and interferon alphas, much less at the time of the subject invention. This further supports his conclusion

that an ordinarily skilled artisan, at the time of the subject invention, could only speculate, and could not reasonably predict, that interferon tau was capable of downregulating IgE production.

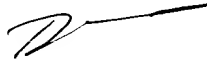
In order to support a *prima facie* case of obviousness, a person of ordinary skill in the art must find both the suggestion of the claimed invention, and a reasonable expectation of success in making that invention, solely in light of the teachings of the prior art. *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Applicants respectfully maintain that the cited references do not teach or suggest the claimed invention. Even assuming, *arguendo*, that the cited references suggested Applicants' claimed invention, Applicants respectfully maintain that the cited references do not provide the requisite "reasonable expectation of success." As Dr. Johnson indicates in his Declaration, an ordinarily skilled artisan at the time of the subject invention could, at best, only speculate as to functional properties of interferon tau in regard to IgE production and would have been just as likely to predict that interferon tau would not downregulate IgE production. Applicants respectfully assert that "speculation" as to a functional property does not satisfy the "reasonable expectation of success" requirement for a *prima facie* case of obviousness. In the absence of an ordinarily skilled artisan having a reasonable expectation that interferon tau could suppress or inhibit IgE production, the claimed invention is not obvious over the cited references. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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DRP/sl

Attachment: Declaration of Howard M. Johnson, Ph.D. Under 37 CFR 1.132